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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,024

02/23/2004

Veli-Matti Lehtola

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03/17/2008

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,024	LEHTOLA ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/17/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- Receipt is acknowledged of applicants' supplemental IDS and amendment, both filed on 17 December 2007.
- The 35 USC 102 and obviousness-type double patenting rejections of the previous Office action are hereby withdrawn in view of the amendment and remarks.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Application No. 2005/0215528 ("Furuya").

Furuya discloses a pharmaceutical composition comprising selective estrogen receptor modulator (SERM) drugs (see paragraph 0006). The disclosed composition is comprised of:

- the solid drug formulation of instant claim 1 (see paragraph 0070);
- the granulates of instant claim 1 (see paragraph 0447);
- the compound of formula 1 (see paragraph 0125);
- the intra-granular excipients of instant claim 1 (see paragraph 0449);
- the ospemifene of instant claim 2 (see paragraph 0125);
- the disintegrant of instant claims 3 and 24 (see paragraph 0448);

- the diluent (lactose) of instant claims 4 and 25 (see paragraph 0070);
- the binder of instant claims 5 and 26 (see paragraph 0448);
- the excipient combination of instant claims 6 and 27(see paragraph 0448);
- the carboxymethylcellulose of instant claims 7 and 28(see paragraph 0452);
- the lactose of instant claims 8 and 29 (see paragraph 0070); and
- the dextrin of instant claims 9 and 30 (see paragraph 0451).

The wet granulation process disclosed in claim 11 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In any event, Furuya discloses a wet granulation process (see paragraph 0494).

Furuya is silent with respect to dissolution profiles. Applicants’ composition, as claimed, is the same as the prior art. As, claimed, applicants’ composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594.

In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

Furuya explains that the disclosed composition is beneficial as a "...preventative or therapeutic method capable of improving preventative or therapeutic effect of a GnRH agonist on various diseases..." See paragraph 0003.

While Furuya does not explicitly teach the ratios of particle sizes of instant claim 1, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine suitable particle size ratios through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Furuya discloses microcapsule formulations (see paragraph 0468) within the size range claimed in instant claim 1, i.e. as small as 2 μm (see paragraph 0085).

Moreover, generally, differences in particle size ratios will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a granulate formulation comprising ospemifiene, as taught by Furuya. One of ordinary skill in the art at the time the invention was made

would have been motivated to make such a composition because it is useful as a preventative or therapeutic method, as explained by Furuya.

* * * * *

Response to Arguments

Applicants' arguments filed 18 December 2007 have been fully considered but they are not persuasive.

1. Applicants argue that, "the Examiner is picking and choosing several variables from a broad generic disclosure in an attempt to arrive at Applicant's specific formulation." See remarks, page 7.

Examiner respectfully submits that the prior art reads on the instant application as claimed. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."). See MPEP 2111.03.

*

2. Applicants argue that the instant application is distinguished from the prior art by the particle sizes and ratios being claimed. See remarks, pages 8-9.

Examiner respectfully submits that Furuya discloses a particle size range within the range claimed, i.e. as small as 2 μm (see paragraph 0085). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie

case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

* * * * *

Conclusion

Applicants' amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone

Art Unit: 1618

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618